

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

comparison effect of Ondansetron and Halopridol and Dexmedetomidine for prophylaxis of postoperative nausea and vomiting in patients undergoing total abdominal hysterectomy

Protocol summary

Study aim

comparison effect of Ondansetron and Halopridol and Dexmedetomidine for prophylaxis of postoperative nausea and vomiting in patients undergoing total abdominal hysterectomy

Design

This study is clinical trial and double blind. 114 patients candidate abdominal hysterectomy referring to Taleghani Hospital of Arak admitted. We divide patients randomly to three groups (Ondansetron, haloperidol, and Dexmedetomidine) by simple randomization method.

Settings and conduct

This study is clinical trial and double blind. 114 patients undergoing abdominal hysterectomy referring to Taleghani Hospital of Arak admitted. Patients assigned randomly to three groups by simple randomization method. The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind).

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients are candidates for abdominal hysterectomy, ASA class I and II, no history of psychiatric and psychology, the absence of Parkinson's disease, motion sickness or chemotherapy history, patients under general anesthesia, patients aged 35-60 years, maximum surgical duration 150 minutes. Exclusion criteria: surgical duration more than 150 minutes

Intervention groups

In the Haloperidol group, 2 milligrams of Haloperidol are given intravenously (equivalent to one milliliter), In the Ondansetron group, 4 milligrams of Ondansetron are given intravenously (equivalent to 1 milliliter) and In the Dexmedetomidine group, 1 micro gram in kilogram of Dexmedetomidine is given intravenously (equivalent to 1 milliliter).

Main outcome variables

vomiting score, nausea, sedation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N84**

Registration date: **2018-08-29, 1397/06/07**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-29, 1397/06/07**

Update count: **0**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-08, 1396/07/16

Expected recruitment end date

2018-10-08, 1397/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
comparison effect of Ondansetron and Halopridol and Dexmedetomidine for prophylaxis of postoperative nausea and vomiting in patients undergoing total abdominal hysterectomy

Public title
comparison effect of Ondansetron and Halopridol and Dexmedetomidine for prophylaxis of postoperative nausea and vomiting in patients undergoing total abdominal hysterectomy

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients are candidates for abdominal hysterectomy ASA class I and II No history of psychiatric and psychology The absence of Parkinson's disease, motion sickness or chemotherapy history Patients under general anesthesia Patients aged 35-60 years Maximum surgical duration 150 minutes
Exclusion criteria:
Surgical duration time more than 150 minutes

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization with random numbers

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient is not aware of the treatment received. Participant and Analyzer are blind (double blind).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethics committee Arak University Of Medical Sciences
Street address
Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3814957558
Approval date
2017-10-08, 1396/07/16
Ethics committee reference number
IR.ARAKMU.REC.1396.111

Health conditions studied

1
Description of health condition studied
abdominal hysterectomy
ICD-10 code
N99.3
ICD-10 code description
Prolapse of vaginal vault after hysterectomy

Primary outcomes

1
Description
Vomiting score
Timepoint
4 and 12 and 24 hours after surgery
Method of measurement
Vomiting score

2
Description
Nausea
Timepoint
After surgery
Method of measurement
Clinical observation

3
Description
Sedation
Timepoint
In recovery
Method of measurement
Ramsay score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the Haloperidol group, 2 milligrams of Haloperidol are given intravenously (equivalent to one milliliter).

Category

Treatment - Drugs

2

Description

Intervention group: In the Ondansetron group, 4 milligrams of Ondonestrone are given intravenously (equivalent to 1 milliliter).

Category

Treatment - Drugs

3

Description

Intervention group: In the Dexmedetomidine group, 1 micro gram in kilogram of Dexomedetomidine is given intravenously (equivalent to 1 milliliter).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Dr Maryam Shokrpour

Street address

Taleghani hospital, Emam Khomeini street

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Email

Mshokrpour@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

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arjmandzadegan@arakmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Maryam Shokrpour

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza Kamali

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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alikalaliir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Lida Ahmadi

Position

student of medicin

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal.

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

dr Alireza Kamali

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments